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Signature: *Karen Buzinski*

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: George Gorodeski)	Examiner: not yet assigned
)	
Serial No.: 10/576,214)	Art Unit: not yet assigned
)	
Filed: April 17, 2006)	Attorney Docket No.: 29519/04004
)	
For: METHOD AND APPARATUS)	
FOR APPLYING MEDICATION)	Confirmation No.: not yet assigned
TO INTERNAL TISSUE)	

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INFORMATION DISCLOSURE STATEMENT

Dear Sir:

In accordance with the duty of disclosure under 37 C.F.R. § 1.56, Applicant hereby notifies the U.S. Patent and Trademark Office of the documents which are listed on the attached PTO/SB/08 A & B forms and/or listed herein and which the Examiner may deem material to patentability of the claims of the above-identified application.

The submission of the listed documents is not intended as an admission that any such document constitutes prior art against the claims of the present application. Applicant does not waive any right to take any action that would be appropriate to antedate or otherwise remove any listed document as a competent reference against the claims of the present application.

FOREIGN LANGUAGE DOCUMENTS

☐ In compliance with the concise explanation requirement under 37 C.F.R. § 1.98(a)(3) for foreign language documents, Applicant encloses herewith a copy of a Communication

from a foreign patent office in a counterpart application citing such documents, together with an English-language version of that portion of the Communication indicating the degree of relevance found by the foreign patent office.

- ☐ In compliance with the concise explanation requirement under 37 C.F.R. § 1.98(a)(3) for foreign language documents, Applicant submits the following explanations:
- ☐ Complete English translations of foreign language documents are being submitted herewith, and therefore no concise explanation for such documents is required.

CERTIFICATION AND FEE PAYMENT INFORMATION

- ☒ The present Information Disclosure Statement is being filed: (1) No later than three months from the application's filing date; (2) Before the mailing date of the first Office Action on the merits (whichever is later); or (3) Before the mailing date of the first Office Action after filing a request for continued examination under 37 C.F.R. § 1.114, and therefore, no Statement under 37 C.F.R. § 1.97(e) or fee under 37 C.F.R. § 1.17(p) is required. If this is not the case, the patent office is hereby authorized to charge any related fee to **Deposit Account No. 030172, order number 29519/04004.**
- ☐ The present Information Disclosure Statement is being filed thirty days or fewer from a Communication from a foreign patent office and Applicant submits the following Statement Under 37 C.F.R. § 1.704(d). Each item of information contained in the Information Disclosure Statement was cited in a Communication from a foreign patent office in a counterpart application and this Communication was not received by any individual designated in 37 C.F.R. § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- ☐ The present Information Disclosure Statement is being filed after the later of three months from the application's filing date and mailing date of the first Office Action on the merits, but before a Final Office Action, Notice of Allowance, or an action that otherwise closes prosecution in the application (whichever is earlier), and therefore Applicant submits the following Statement under 37 C.F.R. § 1.97(e). No fee under 37 C.F.R. § 1.17(p) is required. If this is not the case, the patent office is hereby authorized to charge any related fee to **Deposit Account No. 030172.**
 - ☐ Each item of information contained in this information disclosure statement was cited in a Communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement.
 - ☐ No item of information contained in this information disclosure statement was cited in a Communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the undersigned, having made reasonable

inquiry, was known to any individual designated in 37 CFR § 1.56(c) more than three months prior to the filing of this statement.

- ☐ The present Information Disclosure Statement is being filed (without a Statement under 37 C.F.R. § 1.97(e)) after the later of three months from the application's filing date and the mailing date of the first Office Action on the merits, but before a Final Office Action, Notice of Allowance, or an action that otherwise closes prosecution in the application (whichever is earlier). Accordingly, Applicant submits the fee required under 37 C.F.R. § 1.17(p). The fee is being paid in the following manner:
- ☐ A check is attached in the amount of \$_____ as required under 37 § 1.17(p).
- ☐ The patent office is hereby authorized to charge the amount of \$_____ and any related fee to **Deposit Account No. 030172**.

- ☐ The present Information Disclosure Statement is being filed after the mailing of a final Office Action, Notice of Allowance or an action that otherwise closes prosecution in the application, but on or before the payment of the issue fee. Accordingly, Applicant submits the following Statement under 37 C.F.R. § 1.97(e) along with the fee required under 37 C.F.R. § 1.17(p).
- ☐ Each item of information contained in this information disclosure statement was cited in a Communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement.
- ☐ No item of information contained in this information disclosure statement was cited in a Communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the undersigned, having made reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this statement.

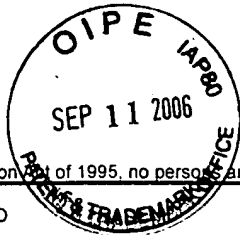
AND, the fee is being paid in the following manner:

- ☐ A check is attached in the amount of \$_____ as required under 37 § 1.17(p).
- ☐ The patent office is hereby authorized to charge the amount of \$_____ and any related fee to **Deposit Account No. 030172**.

Respectfully submitted,

Date: 9/7/06

By: Kenneth J. Smith
Kenneth J. Smith, Reg. No. 45,115
Customer No. 24024
(216) 622-8674



PTO/SB/08A (07-06)

Approved for use through 09/30/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

Application Number	10/576,214
Filing Date	April 17, 2006
First Named Inventor	George Gorodeski
Art Unit	not yet assigned
Examiner Name	not yet assigned
Attorney Docket Number	29519/04004

Sheet 1 of 14

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
		US- 3,797,494	08/09/1971	Zaffaroni	
		US- 4,016,251	04/05/1977	Higuchi et al.	
		US- 4,052,505	10/04/1977	Higuchi et al.	
		US- 4,069,307	01/17/1978	Higuchi et al.	
		US- 4,144,317	03/13/1979	Higuchi et al.	
		US- 4,291,014	09/22/1981	Keith et al.	
		US- 4,321,252	03/23/1982	Kieth et al.	
		US- 4,438,139	03/20/1981	Keith et al.	
		US- 4,976,692	12/11/1990	Atad	
		US- 5,027,830	07/02/1991	Koch	
		US- 5,104,377	04/14/1992	Levine	
		US- 5,164,189	03/11/1991	Farhadieh et al.	
		US- 5,261,878	11/16/1993	Galindo	
		US- 5,295,984	03/22/1994	Contente et al.	
		US- 5,306,249	04/26/1994	Don Michel	
		US- 5,397,307	03/14/1995	Goodin	
		US- 5,460,610	10/24/1995	Don Michel	
		US- 5,505,701	04/09/1996	Anaya Fernandez de Lomana	
		US- 5,508,045	04/16/1996	Harrison	

FOREIGN PATENT DOCUMENTS

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		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				

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This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Sheet

2

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14

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		Number-Kind Code ² (if known)			
		US- 5,508,045	04/16/1996	Harrison et al.	
		US- 5,510,064	04/23/1996	Koch	
		US- 5,529,782	11/03/1994	Staab	
		US- 5,545,210	08/13/1996	Hess et al.	
		US- 5,554,119	09/10/1996	Harrison et al.	
		US- 5,558,642	09/24/1996	Schweich, Jr. et al.	
		US- 5,562,641	10/08/1996	Flomenblit et al.	
		US- 5,607,691	03/04/1997	Hale et al.	
		US- 5,612,051	03/18/1997	Yue	
		US- 5,624,399	04/29/1997	Ackerman	
		US- 5,656,638	08/12/1997	Gaeta et al.	
		US- 5,674,239	10/07/1997	Zadini et al.	
		US- 5,679,647	10/21/1997	Carson et al.	
		US- 5,703,116	12/30/1997	Gaeta et al.	
		US- 5,707,642	01/13/1998	Yue	
		US- 5,713,861	02/03/1998	Vanarthos	
		US- 5,716,340	02/10/1998	Schweich, Jr. et al.	
		US- 5,749,845	05/12/1998	Hildebrand et al.	
		US- 5,750,134	05/12/1998	Scholz et al.	

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Sheet 3 of 14

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		Number-Kind Code ² (if known)			
		US- 5,760,062	06/02/1998	Gaeta et al.	
		US- 5,762,956	06/09/1998	Chien et al.	
		US- 5,767,278	06/16/1998	Gaeta et al.	
		US- 5,770,613	06/23/1998	Gaeta et al.	
		US- 5,780,045	11/08/1996	McQuinn et al.	
		US- 5,800,374	09/01/1998	Beyersdorf	
		US- 5,804,566	09/08/1998	Carson et al.	
		US- 5,811,410	09/22/1998	Falk et al.	
		US- 5,827,834	10/27/1998	Falk et al.	
		US- 5,830,848	11/03/1998	Harrison et al.	
		US- 5,830,877	11/03/1998	Carson et al.	
		US- 5,830,882	11/03/1998	Falk et al.	
		US- 5,833,974	11/10/1998	Teicher	
		US- 5,849,719	12/15/1998	Carson et al.	
		US- 5,852,002	12/22/1998	Falk et al.	
		US- 5,858,365	01/12/1999	Faller	
		US- 5,863,552	01/26/1999	Yue	
		US- 5,863,936	01/26/1999	Gaeta et al.	
		US- 5,869,539	02/09/1999	Garfield et al.	

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		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				

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		Number-Kind Code ² (if known)			
		US- 5,877,216	03/02/1999	Place et al.	
		US- 5,902,817	05/11/1999	Jackson et al.	
		US- 5,908,407	06/01/1999	Frazee et al.	
		US- 5,914,314	06/22/1999	Falk et al.	
		US- 5,929,048	07/27/1999	Falk et al.	
		US- 5,932,560	08/03/1999	Falk et al.	
		US- 5,947,991	09/07/1999	Cowan	
		US- 5,962,521	10/05/1999	Jackson et al.	
		US- 5,972,924	10/26/1999	Keep et al.	
		US- 5,980,804	11/09/1999	Koch	
		US- 5,985,847	11/16/1999	Carson et al.	
		US- 5,985,850	11/16/1999	Falk et al.	
		US- 5,985,851	11/16/1999	Falk et al.	
		US- 6,010,530	01/04/2000	Goicoechea	
		US- 6,022,359	02/08/2000	Frantzen	
		US- 6,037,125	03/14/2000	Hasty	
		US- 6,048,544	04/11/2000	Yue	
		US- 6,048,844	04/11/2000	Falk et al.	
		US- 6,054,444	04/25/2000	Jackson et al.	

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		Number-Kind Code ² (if known)			
		US- 6,054,470	04/25/2000	Betageri et al.	
		US- 6,057,104	05/02/2000	Hasty	
		US- 6,069,135	05/30/2000	Falk et al.	
		US- 6,071,707	06/06/2000	Barton et al.	
		US- 6,071,965	06/06/2000	Jackson et al.	
		US- 6,086,610	07/11/2000	Duerig et al.	
		US- 6,103,275	08/15/2000	Seitz et al.	
		US- 6,119,697	09/19/2000	Engel et al.	
		US- 6,121,252	09/19/2000	Jackson et al.	
		US- 6,133,317	10/17/2000	Hart	
		US- 6,139,538	10/31/2000	Houghton et al.	
		US- 6,150,377	11/21/2000	Lyssikatos et al.	
		US- 6,156,784	12/05/2000	Betageri et al.	
		US- 6,166,079	12/26/2000	Follen et al.	
		US- 6,174,687	01/16/2001	Rajotte et al.	
		US- 6,174,872	01/16/2001	Carson et al.	
		US- 6,186,945	02/13/2001	Gardosi	
		US- 6,194,392	02/27/2001	Falk et al.	
		US- 6,197,327	03/06/2001	Harrison et al.	

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Sheet 6 of 14

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
		US- 6,197,743	03/06/2001	Faller	
		US- 6,246,898	06/12/2001	Vesely et al.	
		US- 6,247,678	06/19/2001	Hines et al.	
		US- 6,264,948	07/24/2001	Wong et al.	
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		US- 6,268,365	07/31/2001	Betageri et al.	
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		US- 6,280,425	08/28/2001	Del Guercio	
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		US- 6,296,832	10/02/2001	Ruoslahti et al.	
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		US- 6,306,841	10/23/2001	Place et al.	
		US- 6,350,463	02/26/2002	Herman et al.	
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		US- 6,372,742	04/16/2002	Chin et al.	
		US- 6,375,676	04/23/2002	Cox	

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Application Number	10/576,214
Filing Date	April 17, 2006
First Named Inventor	George Gorodeski
Art Unit	not yet assigned
Examiner Name	not yet assigned
Attorney Docket Number	29519/04004

Sheet 7 of 14

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		US- 6,384,022	05/07/2002	Jackson et al.	
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		US- 6,395,718	05/28/2002	Slusher et al.	
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		US- 6,414,027	07/02/2002	Neal	
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Sheet	8	of	14
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Sheet 9 of 14

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		Levy S et al "A comparison of the skin permeation of three topical .5% fluorouracil formulations with that of a 5% formulation" Clinical Therapeutics vol 23 no 6 2001 pg 901-7	
		International Search Report from PCT/US04/034782.	
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Art Unit	not yet assigne
Examiner Name	not yet assigned
Attorney Docket Number	29519/04004

Sheet 10

of

14

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Sheet	12	of	14	Application Number	10/576,214
				Filing Date	April 17, 2006
				First Named Inventor	George Gorodeski
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Sheet 14

of 14

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Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		Hodgson, DE, "Shape Memory Alloys", 12 pgs. printed on 10/6/2003 from http://www.sma-inc.com/SMAPaper.html .	
		Machida, Y, et al "Preparation and phase II clinical examination of topical dosage forum for treatment of carcinoma colli containing bleomycin with hydroxypropyl cellulose"	
		(continued from line above) Chem Pharm. Bull, vol. 27, no. 1, 1979, pgs. 93-100.	
		Woolfson, AD, et al, "Bioadhesive cervical patch delivery system for the treatment of cervical intraepithelial neoplasia", PDD 7243 paragraph, study Ulster Cancer Foundation.	
		Strickland, J et al, "Cervical Dysplasia", March 2000, from http://www.catie.ca/facts.nfs/ website printed on 08/04/2003, 5 pgs.	
		Two page brochure, New RepHresh Vaginal Gel, 2002, printed U.S.	
		Noveon Pharmaceutical Polymers booklet, bulletins 1-21, January 2002, 202 pgs.	
		Meyskens, Jr., FL, et al., "Enhancement of Regression of Cervical Intraepithelial Neoplasia II (Moderate Dysplasia) with topically applied All-trans-retinoic acid: a	
		(continued from line above) randomized trial", Journal of the National Cancer Institute, vol. 86, no. 7, April 6, 1994, pgs. 539-543.	
		Manetta, A et al., "B-Carotene Treatment of cervical intraepithelial neoplasia: a phase II study", Cancer Epidemiology, Biomarkers & Prevention, pgs. 929-932, vol 5, 11/1996.	

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